Initial Approval Date: July 10, 2019
Revised Dates: October 9, 2019

**CRITERIA FOR PRIOR AUTHORIZATION**

Adult Rheumatoid Arthritis Agents

**BILLING CODE TYPE** For drug coverage and provider type information, see the KMAP Reference Codes webpage.

**MANUAL GUIDELINES** Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in table 1 below.

Abatacept (Orencia®)
Adalimumab (Humira®, Amjevita™, Cyltezo™, Hyrimoz™, Hadlima™)
Anakinra (Kineret®)
Baricitinib (Olumiant®)
Certolizumab (Cimzia®)
Etanercept (Enbrel®, Erelzi™, Eticovo™)
Golimumab (Simponi®, Simponi Aria®)
Infliximab (Remicade®, Inflectra®, Ixifi™, Renflexis®)
Rituximab (Rituxan®~~, Truxima®~~)
Sarilumab (Kevzara®)
Tocilizumab (Actemra®)
Tofacitinib (Xeljanz®)
Upadacitinib (Rinvoq™)

**GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION:** (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- Must be prescribed by or in consultation with a rheumatologist.[2]
- Patient must have had an adequate trial (at least 90 consecutive days) of or contraindication to methotrexate. If the patient has a contraindication to methotrexate, the patient must have an adequate trial of at least one other conventional therapy or contraindication to all conventional therapies listed in Table 2.[1,2]
- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Prescriber must provide the baseline of ONE of the following ~~criteria~~:
    - Patient has active moderate to severe rheumatoid arthritis disease activity, as defined by:[1]
        - Patient Activity Scale (PAS) or PAS-II score > 3.7
        - Routine Assessment of Patient Index Data (RAPID3) score > 2.0
        - Clinical Disease Activity Index (CDAI) > 10
        - Disease Activity Score (DAS28) score > 3.2
        - Simplified Disease Activity Index (SDAI) score > 11.0
- For all requested immunomodulating biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another immunomodulating biologic or JAK inhibitor listed in Table 3. After discontinuing the current immunomodulating biologic or JAK inhibitor, the soonest that a new immunomodulating biologic or JAK inhibitor will be authorized is at the next scheduled dose.

Table 1. FDA-approved age and dosing limits of Adult Rheumatoid Arthritis (RA) Agents.[3-15-24]

| Medication | Indication(s) | Age | Dosing Limits |
|---|---|---|---|
| **Anti-CD 20** | | | |
| Rituximab (Rituxan®, ~~Truxima®~~)* | Moderate to Severe active RA | ≥ 18 years | 1000 mg IV at weeks 0 and 2 per every 24 week cycle. |
| **Interleukin-1 Inhibitors** | | | |
| Anakinra (Kineret ®) | Moderate to Severe active RA | ≥ 18 years | 100 mg SC once daily. |
| **Interleukin-6 Inhibitors** | | | |
| Sarilumab (Kevzara® | Moderate to Severe active RA | ≥ 18 years | 200 mg SC once every 2 weeks. |
| Tocilizumab (Actemra®) | Moderate to Severe active RA | ≥ 18 years | IV: 8 mg/kg every 4 weeks up to a maximum of 800 mg.<br><br>SC:<br>< 100 kg: 162 mg once every 2 weeks.<br>≥ 100 kg: 162 mg once every week. |
| **Janus Kinase Inhibitors** | | | |
| Baricitinib (Olumiant®) | Moderate to Severe active RA | ≥ 18 years | 2 mg orally once daily. |
| Tofacitinib (Xeljanz®) | Moderate to Severe active RA | ≥ 18 years | 5 mg orally twice daily. |
| Tofacitinib (Xeljanz XR®) | Moderate to Severe active RA | ≥ 18 years | 11 mg orally once daily. |
| Upadacitinib (Rinvoq™) | Moderate to Severe active RA | ≥ 18 years | 15 mg orally once daily. |
| **Selective T-Cell Costimulation Blockers** | | | |
| Abatacept (Orencia®) | Moderate to Severe active RA | ≥ 18 years | IV: at 0, 2 and 4 weeks, then every 4 weeks thereafter<br>< 60 kg: 500 mg.<br>60-100 kg: 750 mg<br>> 100 kg: 1,000 mg<br><br>SC: 125 mg once every week. |
| **Tumor Necrosis Factor-Alpha (TNF-α) Blockers** | | | |
| Adalimumab (Humira®, Amjevita™, Cyltezo™, Hyrimoz™, Hadlima™)~~}~~ | Moderate to Severe active RA | ≥ 18 years | 40 mg SC every week. |
| Certolizumab (Cimzia®) | Moderate to Severe active RA | ≥ 18 years | 400 mg initially SC at weeks 0, 2, and 4 followed by 200 mg every other week or 400 mg every 4 weeks. |
| Etanercept (Enbrel®, Erelzi™, Eticovo™) | Moderate to Severe active RA | ≥ 18 years | 50 mg SC once weekly. |
| Golimumab (Simponi®) | Moderate to Severe active RA | ≥ 18 years | 50 mg SC once monhtly. |
| Golimumab (Simponi Aria®) | Moderate to Severe active RA | ≥ 18 years | 2 mg/kg IV at weeks 0, 4, then every 8 weeks thereafter |
| Infliximab (Remicade®, Renflexis™, Inflectra®, Ixifi™) | Moderate to Severe active RA | ≥ 18 years | 3 mg/kg IV at 0, 2, and 6 weeks, then every 8 weeks. |

SC: subcutaneous. IV: intravenous. *Truxima®and Ruxience™ are rituximab biosimilars, but are currently not indicated for RA.

**LENGTH OF APPROVAL (INITIAL):** 12 months

**CRITERIA FOR RENEWAL PRIOR AUTHORIZATION:** (must meet all of the following)

- Prescriber must provide at least ONE of the following response measure(s):
  - Low disease activity or remission.[1]
    - PAS or PAS-II score ≤ 3.7
    - RAPID3 score ≤ 2.0
    - CDAI score ≤ 10.0
    - DAS28 score ≤ 3.2
    - SDAI score ≤ 11.0
- Must not exceed dosing limits listed in Table 1.
- For all requested immunomodulating biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another immunomodulating biologic or JAK inhibitor listed in Table 3. After discontinuing the current immunomodulating biologic or JAK inhibitor, the soonest that a new immunomodulating biologic or JAK inhibitor will be authorized is at the next scheduled dose.

**LENGTH OF APPROVAL (RENEWAL):** 12 months

**FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:**

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

**LENGTH OF APPROVAL (INITIAL AND RENEWAL):** 12 months

Table 2. List of conventional therapy in the treatment of RA.[1]

| Non-Biologic DMARDs | |
|---|---|
| **Generic Name** | **Brand Name** |
| Hydroxychloroquine | Plaquenil® |
| Leflunomide | Arava® |
| Methotrexate | Trexall®, Rheumatrex®, Otrexup®, Rasuvo® |
| Sulfasalazine | Azulfidine® |

Table 3. List of immunomodulating biologic agents/janus kinase inhibitors (agents not to be used concurrently).

| Immunomodulating Biologic Agents/Janus Kinase Inhibitors | | |
|---|---|---|
| Actemra® (tocilizumab) | Hyrimoz™ (adalimumab-adaz) | Ruxience™ (rituximab-pvvr) |
| Amevive® (alefacept) | Ilaris® (canakinumab) | Siliq® (brodalumab) |
| Amjevita™ (adalimumab-atto) | Ilumya™ (tildrakizumab-asmn) | Simponi® (golimumab) |
| Cimzia® (certolizumab) | Inflectra® (infliximab-dyyb) | Simponi Aria (golimumab) |
| Cinqair® (reslizumab) | Ixifi™ (infliximab-qbtx) | Skyrizi™ (Risankizumab) |
| Cosentyx® (secukinumab) | Kevzara® (sarilumab) | Stelara® (ustekinumab) |
| Cyltezo™ (adalimumab-adbm) | Kineret® (anakinra) | Taltz® (ixekizumab) |
| Dupixent® (benralizumab) | Nucala® (mepolizumab) | Tremfya® (guselkumab) |
| Enbrel® (etanercept) | Olumiant® (baricitinib) | Truxima® (rituximab-abbs) |
| Entyvio® (vedolizumab) | Orencia® (abatacept) | Tysabri® (natalizumab) |
| Erelzi™ (etanercept-szzs) | Remicade® (infliximab) | Xeljanz® (tofacitinib) |
| Eticovo® (etanercept-ykro) | Renflexis® (infliximab-abda) | Xeljanz XR® (tofacitinib) |
| Fasenra™ (benralizumab) | Rinvoq™ (upadacitinib) | Xolair® (omalizumab) |
| Hadlima™ (adalimumab-bwwd) | Rituxan® (rituximab) | |

| | | |
|---|---|---|
| Humira® (adalimumab) | Rituxan Hycela™ (rituximab/hyaluronidase) | |

Notes:

| | |
|---|---|
| Rinvoq™ (upadacitinib) | May be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). Use in combination with biologic DMARDs or potent immunosuppressants (eg, azathioprine, cyclosporine) is not recommended. |

References


1. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2016; 68(1):1-26. https://www.rheumatology.org/Practice-Quality/Clinical-Support/Clinical-Practice-Guidelines/Rheumatoid-Arthritis . Accessed 5/30/19.
2. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. Ann Rheum Dis 2017; 76:960-77. Available at https://www.eular.org/recommendations_management.cfm . Accessed 6/11/19.
3. Enbrel (etanercept) [package insert]. Thousand Oaks, CA: Immunex Corp., Amgen; Nov 2017.
4. Remicade (infliximab) [package insert]. Horsham, PA: Janssen Biotech, Inc; Jun 2018.
5. Humira (adalimumab) [package insert]. North Chicago, IL: AbbVie Inc.; Dec 2018.
6. Cimzia (certolizumab) [package insert]. Smyrna, GA: UCB, Inc.; Mar 2019.
7. Simponi (golimumab) [package insert]. Horsham, PA: Janssen Biotech, Inc.; May 2018.
8. Simponi Aria (golimumab) [package insert]. Horsham, PA: Janssen Biotech, Inc.; Feb 2018.
9. Kineret (anakinra) [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB; Jun 2018.
10. Orencia (abatacept) [package insert]. Princeton, NJ: Bristol-Myers Squibb Compant; Mar 2019.
11. Rituxan (rituximab) [package insert]. South San Francisco, CA: Genentech, Inc..; Jan 2019.
12. Actemra (tocilizumab) [package insert]. South San Francisco, CA: Genentech, Inc..; Apr 2019.
13. Kevzara (sarilumab) [package insert]. Bridgewater, NJ: Sanofi-Aventis US LLC; Apr 2018.
14. Xeljanz (tafacitinib) [package insert]. New York, NY: Pfizer Labs; Oct 2018.
15. Olumiant (baricitinib) [package insert]. Indianapolis, IN: Lilly USA; May 2018.
16. Rinvoq (upadacitinib) [prescribing information]. North Chicago, IL: AbbVie Inc; August 2019.
17. Amjevita (adalimumab-atto) [prescribing information]. Thousand Oaks, CA: Amgen Inc; March 2018.
18. Cyltezo (adalimumab- adbm) [prescribing information]. Ridgefield, CT; Boehringer Ingelheim Pharmaceuticals Inc: August 2017.
19. Hadlima (adalimumab-bwwd) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; July 2019.
20. Erelzi (etanercept) [prescribing information]. Princeton, NJ: Sandoz Inc; January 2018.
21. Eticovo (etanercept) [prescribing information]. Republic of Korea: Samsung Bioepis Co., Ltd. Apr 2018.
22. Inflectra (infliximab-dyyb) [prescribing information]. New York, NY: Pfizer; September 2016.
23. Renflexis (infliximab-abda) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; June 2019.
24. Ixifi (infliximab-qbtx) [prescribing information]. New York, NY: Pfizer; December 2017.


DRUG UTILIZATION REVIEW COMMITTEE CHAIR

PHARMACY PROGRAM MANAGER

DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

_____ _____

DATE DATE